EXHIBIT 17

2248/62942-BA JPW/BJT

Application No.	Applicant(s)	
11/520,556	OLSON ET AL.	
Examiner	**Art Unit**	
Jeffrey S. Parkin	1648	

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status Response-A-2/10/09 Appeal/Final Rej. Resp Due: 4/27/09 4mo-5/27/09 5mo-6/27/09 6mo-7/27/09

1)☒ Responsive to communication(s) filed on *29 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-68 and 70-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-68 and 70-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/29/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants: Graham P. Allaway et al.
Serial No.: 09/888,938
Filed: June 25, 2001
Exhibit 17

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 29 September, 2008. Claims 52-68 and 70-72 are pending in the instant application.

Information Disclosure Statement

The information disclosure statement filed 29 September, 2008, has been placed in the application file and the information referred to therein has been considered.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The previous rejection of claims 60 and 70 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is hereby withdrawn in response to Applicants' amendment.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Biological Deposit Requirement

The previous rejection of claims 52 and 61 under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure for the claimed invention with respect to Mab PA14, and its attendant hybridoma, is hereby withdrawn in response to Applicants' reply.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 52-57 and 60 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Olson *et al.* (1999) and Kilby *et al.* (1998). As previously set forth, the claims are directed toward a method of inhibiting HIV-1 infection through the administration of Mab PA14 and T20. Olson and colleagues

describe the preparation and characterization of Mab PA14. This is an anti-CCR5 antibody that displays potent inhibition of HIV-1 entry and fusion. Kilby and associates demonstrate that T20 (or DP178) is a potent peptide fusion inhibitor of HIV-1. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to combine Mab PA14, as taught by Olson *et al.* (1999), with T20, as disclosed by Kilby *et al.* (1998), since this would provide a potent antiviral composition. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 U.S.P.Q. 1069, 1072 (C.C.P.A. 1980). The inclusion of two different antivirals would also be expected to delay the development of drug-resistant variants. It would also have been *prima facie* obvious to determine suitable routes of administration and dosages.

Applicants traverse and submit that the combination of Mab PA14 and T20 provided a significant and unexpected synergistic effect that was not appreciated by the prior art. First, applicants are reminded that the claims are simply directed toward a combination treatment involving Mab PA14 and T20. There is no requirement that the combination act in a synergistic manner. Second, a greater than additive effect is not necessarily sufficient to overcome a *prima facie* case of obviousness because such an effect can either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte The NutraSweet Co.*, 19 U.S.P.Q.2d 1586 (Bd. Pat. App. & Inter. 1991). Mab PA14 and T20 were both potent inhibitors of HIV-1 infection. Therefore,

it is not surprising that a synergistic effect would be observed when these compositions were combined into a single treatment regimen.

Claims 58 and 59 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Olson *et al.* (1999) and Kilby *et al.* (1998), as applied *supra* to claims 52-57 and 60, and further in view of Wu and Mackay (1998). Wu and Mackay provide humanized and chimeric monoclonal antibodies. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to prepare humanized/chimeric PA14 Abs since this would lead to more effective therapeutic molecules.

Claims 61-67 and 70 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Olson *et al.* (1999), Kilby *et al.* (1998), and Gauduin *et al.* (1996). The claims are directed toward a method of inhibiting HIV-1 infection through the administration of Mab PA14, T20, and CD4-IgG2. Olson and colleagues describe the preparation and characterization of Mab PA14. This is an anti-CCR5 antibody that displays potent inhibition of HIV-1 entry and fusion. Kilby and associates demonstrate that T20 (or DP178) is a potent peptide fusion inhibitor of HIV-1. Gaudin and coworkers teach that CD4-IgG2 is a potent neutralizer of HIV-1. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to combine Mab PA14, as taught by Olson *et al.* (1999), with T20, as disclosed by Kilby *et al.* (1998), and CD4-IgG2, as provided by Gauduin *et al.* (1996), since this would provide a potent antiviral composition. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 U.S.P.Q. 1069, 1072

(C.C.P.A. 1980). The inclusion of two different antivirals would also be expected to delay the development of drug-resistant variants. It would also have been *prima facie* obvious to determine suitable routes of administration and dosages.

Applicants traverse and submit that the combination of Mab PA14, T20, and CD4-IgG2 provided a significant and unexpected synergistic effect that was not appreciated by the prior art. First, Applicants are reminded that the claims are simply directed toward a combination treatment involving Mab PA14 and T20. There is no requirement that the combination act in a synergistic manner. Second, a greater than additive effect is not necessarily sufficient to overcome a *prima facie* case of obviousness because such an effect can either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte The NutraSweet Co.*, 19 U.S.P.Q.2d 1586 (Bd. Pat. App. & Inter. 1991). Mab PA14, T20, and CD4-IgG2 are all potent inhibitors of HIV-1 replication. Therefore, it is not surprising that a synergistic effect would be observed when these compositions were combined into a single treatment regimen.

Claims 68 and 69 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Olson *et al.* (1999), Kilby *et al.* (1998), and Gauduin *et al.* (1996), as applied *supra* to claims 61-67 and 70, and further in view of Wu and Mackay (1998). Wu and Mackay provide humanized and chimeric monoclonal antibodies. Therefore, it would have been *prima facie* obvious to one of

ordinary skill in the art at the time of the invention to prepare humanized/chimeric PA14 Abs since this would lead to more effective therapeutic molecules.

Claim 71 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kilby *et al.* (1998) in view of Olson *et al.* (1999). The claims are directed toward a method of inhibiting HIV-1 infection through the administration of T20 and Mab PA14. Kilby and associates demonstrate that T20 (or DP178) is a potent peptide fusion inhibitor of HIV-1. Olson and colleagues describe the preparation and characterization of Mab PA14. This is an anti-CCR5 antibody that displays potent inhibition of HIV-1 entry and fusion. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to combine T20, as taught by Kilby *et al.* (1998), with Mab PA14, as disclosed by Olson *et al.* (1999), since this would provide a potent antiviral composition. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 U.S.P.Q. 1069, 1072 (C.C.P.A. 1980). The inclusion of two different antivirals would also be expected to delay the development of drug-resistant variants. It would also have been *prima facie* obvious to determine suitable routes of administration and dosages.

Claim 72 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kilby *et al.* (1998) and Olson *et al.* (1999), as applied *supra* to claim 71, and further in view of Wu and Mackay (1998). Wu and Mackay provide humanized and chimeric monoclonal antibodies. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the

invention to prepare humanized/chimeric PA14 Abs since this would lead to more effective therapeutic molecules.

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 U.S.P.Q.2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 U.S.P.Q.2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 U.S.P.Q. 761 (C.C.P.A. 1982); *In re Vogel*, 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970); and *In re Thorington*, 418 F.2d 528, 163 U.S.P.Q. 644 (C.C.P.A. 1969). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) or § 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must

fully comply with 37 C.F.R. § 3.73(b).

Provisional Rejections

Claims 52-55, as well as new claims 71 and 72, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33-55 of copending Application No. 11/316,078. Although the conflicting claims are not identical, they are not patentably distinct from each other. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Applicants have indicated that they will respond appropriately upon the identification of allowable subject matter.

Claims 52-60, as well as new claims 71 and 72, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32 and 33 of copending Application No. 11/491,330, in view of Kilby *et al.* (1998). Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the '330 application are directed toward methods of inhibiting HIV by administering a Mab (PRO14, or PA14) and fusion inhibitor. Kilby and associates demonstrate that T20 (or DP178) is a potent peptide fusion inhibitor of HIV-1. Therefore it would have been prima facie obvious to combine PRO140/PA14 with T20/DP178 to make a potent antiviral composition. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Applicants have indicated that they will respond appropriately upon the identification of allowable subject matter.

Claim 52, as well as, new claim 71, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 75, 76, 79, 90, 91, and 95 of copending Application No. 11/581,945. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the '945 application are directed toward methods of treating HIV-1 infection through the administration of PRO140/PA14 and T20 and are not patentably distinct from the claims in the instant application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Applicants have indicated that they will respond appropriately upon the identification of allowable subject matter.

Non-provisional rejections

Claim 52, as well as new claim 71, are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23 and 24 of U.S. Patent No. 7,060,273. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the '273 patent are directed toward similar subject matter (i.e., reducing HIV-1 viral load by administering a composition comprising PA14 and T20) and are not patentably distinct. Applicants have indicated that they will respond appropriately upon the identification of allowable subject matter.

Action Is Final, Necessitated by Amendment

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS**

ACTION IS MADE FINAL. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information

refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

/Jeffrey S. Parkin/

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

21 January, 2009

UNITED STATES PATENT AND TRADEMARK OFFICE

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11/520,556	09/12/2006	William C. Olson	62942-BA	8572

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.